REMARKS

Reconsideration and withdrawal of the rejections of this application are respectfully requested in view of the amendments and remarks herewith.

Claims 1-11 are pending in the subject application. By this amendment, Applicants have amended claim 3 and canceled claims 12-55 without prejudice. Applicant reserves the right to pursue the subject matter of the canceled claims in one or more divisional applications.

No new matter is added.

I. CLAIM OBJECTIONS

Claim 3-6 were objected to for informalities.

Without prejudice and in the interests for facilitating prosecution, Applicants have amended the claims to overcome this objection.

In view of the amendments, Applicants respectfully request reconsideration and withdrawal of the claim objections.

II. REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 1, 2 and 7-10 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention. Applicants respectfully traverse the rejection.

The Examiner alleges that the terms "ester, amide or prodrug thereof" in claims 1, 2, and 7-10 have indefinite metes and bounds and is unclear where the site is for the ester, amide, or prodrug. (*Office Action* at 3). Applicants submit that the terms "ester, amide and prodrug" is not unclear in view of the specification. Applicants respectfully refer the Examiner to page 14 of the specification in which Applicants describe the use of the terms "ester, amide and prodrugs". Specifically, Applicants provide examples of esters and amides as well as the method of preparing such esters and amides. For instance, examples of pharmaceutically acceptable, non-toxic esters include, without limitation, C_{1-6} alkyl esters, C_{5-7}cycloalkyl esters, and arylalkyl esters which may be prepared by conventional methods, as described, for example, in M. B. Smith and J. March, March's Advanced Organic Chemistry (5.sup.th Ed. 2001). (See page 14, paragraph 0052). Further, examples of pharmaceutically acceptable, non-toxic amides include, without limitation, those derived from ammonia, primary C_{1-6} alkyl amines, and secondary C_{1-6} dialkyl or heterocyclyl amines which may be prepared by conventional methods, as described, for example, in March's Advanced Organic Chemistry. (See page 14, paragraph 0053).

In addition, Applicants refer the Examiner to page 14 of the specification which provides that prodrugs "refer to compounds that having little or no pharmacological activity that can, when metabolized in vivo, undergo conversion to claimed or disclosed compounds having desired activity." (See page 14, paragraph 0054). Further, Applicants specifically refer the Examiner to the following well known text books: T. Higuchi and V. Stella, "Pro-drugs as Novel Delivery Systems, ACS Symposium Series 14 (1975), E. B. Roche (ed.), Bioreversible Carriers in Drug Design (1987), and H. Bundgaar, Design of Prodrugs (1985) for a discussion of prodrugs. Applicants also submit that the preparation of prodrugs have been described in numerous text books of medicinal chemistry. Hence, the specification clearly describes the metes and bounds of the terms "ester, amide and prodrug".

Thus, Applicants submit that a skilled artisan, based on the written description and the common knowledge in the art, would understand the potential sites for esters, amides, and prodrugs of formula I.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. §112, second paragraph as to claims 1, 2 and 7-10.

III. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 1, 2, and 7-10 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner asserts that the specification does not describe a possible ester, amide or prodrug and does not provide starting materials or reaction conditions for such a conversion. (*Office Action* at 4). Applicants respectfully traverse the rejection.

Applicants submit that the terms "ester, amide and prodrug" is not unclear in scope in view of the specification. Applicants respectfully refer the Examiner to page 14 of the specification in which Applicants describe the use of the terms "ester, amide and prodrugs". As mentioned above, the specification describes numerous examples and methods of preparing esters, amides and prodrugs, which would be understood by those so skilled in the art. Thus, Applicants submit that a skilled artisan, based on the written description and the common knowledge in the art, would understand the processes for making esters, amides and prodrugs as claimed.

Applicants respectfully submit that the written description requirement is satisfied when the applicant conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. MPEP 2163.02. Applicants submit that one of ordinary skill would readily determine that Applicants possessed the invention of claims 1, 2, and 7-10 at the time the application was filed based on the above description.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. §112, second paragraph as to claims 1, 2 and 7-10.

IV. REJECTION UNDER 35 U.S.C. §103

Claims 1, 2 and 7-11 stand rejected as allegedly obvious under 35 U.S.C. § 103 over Small et al. ("Small") in view of U.S. Patent No. 6,627,634 to Himmelsbach et al. ("Himmelsbach"). Applicants respectfully traverse the rejection under 35 U.S.C. § 103(a) in view of the following remarks.

Establishment of *prima facie* obviousness requires three conditions. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); *In re Dillon*, 919 F.2d 688, at 692, 16 USPQ2d 1987, at 1901; *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984) ("The prior art must provide one of ordinary skill in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compound.").

Applicants respectfully submit that the Examiner has not shown where the motivation to establish a *prima facie* case of obvious is found in Small.

Specifically, the Examiner asserts that "the disclosed process differs from the claimed process by not having a G (or protecting) group on the amino (of the anilino)" and that "Himmelsbach et al. discuss the possibility of having a protecting group on the amino. . ." (Emphasis added) (*Office Action* at 5). Further, the Examiner asserts that "the skilled chemist would have been motivated to modify the process in Small et. al. by having a protecting group on the amino (of the anilno)." *Id.*

Applicants' respectfully submit that the Examiner has failed to point to any teaching or suggestion in Small and/or Himmelsbach to practice the claimed process in the present application. The Examiner merely recites bits and pieces from Small and Himmelsbach using Applicants' disclosure as the blue print to arrive at the claimed invention. This is improper.

For example, the Examiner relies upon a single passage in Himmelsbach which the Examiner admits is a mere possibility. Although the passage relates to protecting groups, the Examiner does not provide any motivation in Small and/or Himmelsbach to suggest the claimed process of the instant application. It is submitted that the rejections under 35 USC 35 U.S.C. § 103(a) are based on speculation or the unsupported opinion of the Examiner derived by hindsight knowledge of Applicant's specification since there is no teaching or suggestion in the references to make the combinations alleged by the Examiner to be obvious. The Examiner is suggesting an "obvious to try" concept. But, such a concept does not render Applicant's invention as presently claimed unpatentable.

Accordingly, the Examiner has not met the standard for an obviousness rejection based upon the well-established rules of law. No where has the Examiner provided a motivation to modify the teachings of Small and/or Himmelsbach to arrive at the claimed invention.

Based on the above arguments, Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. § 103(a).

CONCLUSION

In view of the remarks and amendments herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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